K050389
1 of 2

MAY 25 2005

510(k) Summary

(as required per 21 CFR 807.92)

General Provisions

Submitter's Name and Address	Boston Scientific Corporation Two Scimed Place Maple Grove, Minnesota 55311
Contact Person	Angela Byland Manager, Regulatory Affairs (763) 494-2887
Classification Name	Percutaneous Transluminal Angioplasty Balloon Dilatation Catheter (21CFR Part 870.1250)
Classification	Class II
Common or Usual Name	Balloon Dilatation Catheter
Proprietary Name	Boston Scientific Ultra-soft™ SV Balloon Dilatation Catheter

Predicate Device

Boston Scientific Corporation Ultra-soft™ SV Balloon Dilatation Catheter (K021735; cleared August 8, 2002)

Device Description

The Ultra-soft™ SV Balloon Dilatation Catheter is a Monorail™ catheter with a balloon near the distal tip. The balloon is designed to provide an inflatable segment of known diameter and length at recommended pressures. The distal segment of the balloon catheter is dual lumen and coaxial. The outer lumen is used for inflation of the balloon. The wire lumen permits the use of guidewires (≤0.018 in / 0,46 mm) to facilitate advancement of the catheter to and through the stenosis to be dilated. The Ultra-soft™ SV Balloon Dilatation Catheter will be available in the sizes summarized in Table 1.

K050399
2 of 2

Section 4 Summary of Safety and Effectiveness

Device Description (continued)

Table 1: Ultra-soft™ SV Size Matrix

Length Balloon/Catheter	Balloon Diameter						
	4.0mm	4.5mm	5.0mm	5.5mm	6.0mm	6.5mm	7.0mm
15 mm/90 cm	X	X	X	X	X	X	X
15 mm/150 cm	X	X	X	X	X	X	X
20 mm/90 cm	X	X	X	X	X	X	X
20 mm/ 150 cm	X	X	X	X	X	X	X

Intended Use

The proposed Ultra-soft™ SV Balloon Dilatation Catheter is indicated for percutaneous transluminal angioplasty (PTA) of the carotid, iliac, femoral, ilio-femoral, popliteal and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

Technological Characteristics

The Ultra-soft™ SV Balloon Dilatation Catheter is substantially equivalent in design, packaging, fundamental technology, manufacturing, sterilization and intended use as compared to the predicate Boston Scientific Ultra-soft™ SV Balloon Dilatation Catheter.

Conclusion

Based on the Indications for Use, technological characteristics, and safety and performance testing, the Ultra-soft™ SV Balloon Dilatation Catheter has been shown to be acceptable for its intended use and is considered to be substantially equivalent to the Ultra-soft™ Balloon Dilatation Catheter (K021735; cleared August 8, 2002)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 25 2005

Boston Scientific Corporation
c/o Ms. Angela Byland
Manager, Regulatory Affairs
Two Scimed Place
Maple Grove, MN 55311-1566

Re: K050389
Ultra-Soft SV Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (Two)
Product Code: DQY
Dated: May 11, 2005
Received: May 12, 2005

Dear Ms. Byland:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050389

Device Name: Ultra-soft™ SV Balloon Dilatation Catheter

Indications For Use:

The Ultra-soft™ SV Balloon Dilatation Catheters are indicated for percutaneous transluminal angioplasty (PTA) of the carotid, iliac, femoral, ilio-femoral, popliteal, and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K050389